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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

KAY ECKLER, On Behalf of Herself and All Others Similarly Situated,

Plaintiff,

vs.

WAL-MART STORES, INC., a Delaware corporation,

Defendant.

Case No. 3:12-cv-00727-LAB-MDD
Hon. Judge Larry Alan Burns
Courtroom 9

**DEFENDANT WAL-MART STORES, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS SECOND AMENDED COMPLAINT**

**[Fed. R. Civ. P. 8, 9(b), 12(b)(6)]**

Hearing Date: March 11, 2013
Hearing Time: 11:30 a.m.
Hearing Location: Courtroom 9

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Defendant Wal-Mart Stores, Inc. ("Wal-Mart") respectfully submits this memorandum in support of its motion to dismiss the Second Amended Class Action Complaint ("the Complaint" or "Cmplt.") with prejudice pursuant to Federal Rules of Civil Procedure 8, 9(b) and 12(b)(6). Wal-Mart also moves to strike certain immaterial allegations from the Complaint pursuant to Rule 12(f).

## PRELIMINARY STATEMENT

In its Memorandum Opinion and Order dismissing the First Amended Complaint, this Court admonished Plaintiff Kay Eckler ("Plaintiff") to keep in mind three things if she chose to amend her complaint challenging statements on the Equate Glucosamine Chondroitin MSM Advanced Triple Strength product ("Equate" or the "Product"). *Eckler v. Wal-Mart Stores, Inc.*, No. 12cv727, 2012 U.S. Dist. LEXIS 157132, at *31-33 (S.D. Cal. Nov. 1, 2012). First, Plaintiff would need to "clean[] up" her Unfair Competition Law ("UCL") claims to differentiate between the "fraudulent," "unfair," and "unlawful" prongs of that statute, and if she "intends to plead a UCL claim based upon unlawful and unfair conduct, she must do more than simply say so." *Id.* at *31-32. Second, to the extent that she bases her allegations on her own experience with the Product, she would need to "say far more than, in essence, 'I took Equate and didn't feel any better.'" *Id.* at *32. And third, in order to address "the Court's biggest problem with her complaint," she would need to "do more to explain why the studies she cites regarding glucosamine and osteoarthritis contradict the actual representations at issue." *Id.* Plaintiff elected to amend her complaint, but she has failed to rectify these critical shortcomings.

First, Plaintiff has not added any factual allegations that can support claims under the unlawful or unfair prongs of the UCL. The Complaint now includes a series of allegations regarding alleged non-compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. §§ 301 *et seq.*) that appear to be directed to the unlawful prong, but she cannot predicate such a claim on alleged violations of a statue under which there is no private right of action. Striking those allegations leaves only a formulaic recitation of the statute's elements, which this Court has already recognized is insufficient to state a claim.

Second, Plaintiff has not added sufficient allegations regarding her experience with Equate to make her claims any less speculative. *See Eckler*, 2012 U.S. Dist. LEXIS 157132, at *8 n.2 (noting that the claim that "she took Equate casually and just didn't feel much better . . . makes her own claims just as speculative as she alleges Equate's benefits are."). In dismissing the First Amended Complaint, this Court noted that the effectiveness of the Product is "probably influenced by a number of variables," but posited several ways in which Plaintiff might have accounted for such variables in determining that the Product did not work for her. *Id.* Presumably because she cannot do so, she has not added any such allegations.

Third, Plaintiff still fails to answer the Court's central question: "What do studies showing that glucosamine doesn't alleviate the symptoms of osteoarthritis in the hip and knee have to do with the representations of a dietary supplement, explicitly *not* intended to treat a disease, that it is formulated to support joint comfort, rebuil[d] cartilage, and lubricate joints?" *Id.* at *32-33. Plaintiff has not pointed to any study testing Equate for its efficacy in providing the benefits actually stated on Product label. Rather, Plaintiff continues to rely on irrelevant osteoarthritis studies testing one or two of the ingredients for their efficacy in providing a benefit never promised—and expressly disclaimed—on the label: treatment of the disease of osteoarthritis. Plaintiff's only solution to this problem is to invite this Court to make unwarranted, implausible, and unreasonable inferences that ignore the Product's actual representations. Plaintiff's new allegations merely confirm that "the disconnect is as wide as the Court suspect[ed]," "[a]nd that means dismissal is proper." *Id.* at *33-34 n.10.

In dismissing the First Amended Complaint, the Court offered Plaintiff guidance on what shortcomings needed to be corrected in order to state a claim. With her Second Amended Complaint, Plaintiff has demonstrated that these shortcomings are insurmountable. This Court should again dismiss the Complaint, and because no further amendment would salvage Plaintiff's claims, should now do so with prejudice.

## SUMMARY OF THE COMPLAINT

Allegations About the Plaintiff. Plaintiff is a resident of San Diego County, California who claims to have purchased a single bottle of Equate in "approximately December 2011" at a

Wal-Mart in Oceanside, California. Cmplt. ¶ 16. She claims that she used the Product for two months to "alleviate stiffness and pain in her shoulder, neck and right wrist," and that the Product did not "rebuild her cartilage, lubricate her joints or improve her joint comfort." *Id.* Like her prior complaint, Plaintiff is still alleging "in essence, 'I took Equate and didn't feel any better.'" *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *32. She does not claim that she used the Product as directed, does not allege what caused the stiffness and pain (*i.e.*, whether she has arthritis or another disease, which the Product is expressly not intended to treat or cure), and does not claim that the Product is unsafe or that she suffered any physical injury. Thus, her claim is still "that she took Equate casually and just didn't feel much better, but that makes her own claims just as speculative as she alleges Equate's benefits are." *Id.* at *8 n.2.

Allegations About the Product Representations. Plaintiff alleges that she "was exposed to and saw" representations that Equate is "'formulated to help' 'support joint comfort' 'rebuild cartilage' and 'lubricate joints'" by "reading the packaging and labeling,"[1] which she dubs the "'joint health benefit representations.'" Cmplt. ¶¶ 1, 16. While she alleges that Wal-Mart engages in "an extensive, widespread, comprehensive, and uniform nationwide marketing campaign," she nowhere alleges that she saw (or relied on) any representations apart from the so-called "joint health benefit representations" on the Product's packaging. *Id.* ¶ 1.

Undeterred by this Court's finding that "[i]t's hard to see how the statement 'This product is not intended to diagnose, treat, cure, or prevent any disease' is not a qualification or limitation," *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *27, Plaintiff persists in alleging that "no limitations accompany Defendant's joint health benefit representations" such that the "take-away" is that Equate promises that it will "help rebuild cartilage, lubricate joints and support joint comfort" for "all joints in the human body, for adults of all ages and for all manner and stages of

[1] A color copy of the Product's packaging is submitted as Exhibit A. Plaintiff does not dispute that the actual packaging, reproduced in the Complaint and central to the claims, can be considered by the Court on this motion to dismiss. *See, e.g., Temple v. Adams*, No. CV-F-04-6716, 2006 U.S. Dist. LEXIS 97616 (E.D. Cal. Aug. 22, 2006), at *27 ("[W]hen a written instrument contradicts allegations in a complaint to which it is attached, the exhibit trumps the allegations.") (Internal quotations omitted).

joint ailments." Cmplt. ¶¶ 1, 8, 22. Thus, Plaintiff still "imputes to Wal-Mart language it doesn't use." *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *12 n.4.

Allegations About Wal-Mart's Purported Lack of Substantiation and the Clinical Studies. Plaintiff bases her allegation that she was deceived into purchasing the Product on the assertion that Wal-Mart does not have "competent scientific substantiation" for the representations on the Product, and that the "scientific evidence affirmatively establishes" that the Product is ineffective. Cmplt. ¶ 3. Plaintiff still challenges the efficacy of the Product based on the assertion that "numerous clinical studies" allegedly have found one ingredient—glucosamine—to be ineffective in treating osteoarthritis. Cmplt. ¶ 20, ¶ 21 ("the focus of this action is on . . . glucosamine"), ¶ 22. The Product, however, includes multiple ingredients, not just glucosamine. *See* Ex. A; *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *23 ("[N]one of these studies actually involved Equate. As its packaging makes clear, Equate contains a number of ingredients . . . . [a]nd it is that overall formulation that's behind the representations at issue.")

The "scientific evidence" that Plaintiff continues to rely on is a handful of "clinical cause and effect studies" examining the effectiveness of other formulations in treating osteoarthritis. *Id.* ¶¶ 9, 24-32. The Complaint still does not (because it cannot) allege that any of these studies tested the actual Product or its formulation or even all of its ingredients, nor does it allege (because it cannot) that the Product states that it should be used to treat osteoarthritis. On the contrary, the Product's label *does not* refer to arthritis but *does* state that the Product is "not intended to diagnose, treat, cure, or prevent any disease." Moreover, the label makes clear that the Product is intended for the *maintenance* of *healthy* joints by stating that "[o]verexertion, the natural aging process and everyday wear and tear can take their toll. Glucosamine Chondroitin Complex has a proprietary blend of ingredients that support healthy joints," that the Product is "designed for those individuals who are serious about protecting and maintaining their joint health," and that the Product "helps protect cartilage and helps maintain the cellular components within joints." *Id.* ¶ 2; Ex. A; *see also Eckler*, 2012 U.S. Dist. LEXIS 157132, at *28 (reference on label to "'[o]verexertion, the natural aging process and everyday wear and tear'" is "yet

another way of making th[e] point clear," along with the disclaimer, that the Product is not intended to treat the disease of osteoarthritis).

The New "Disease Claim" Allegations. In an effort to plead around the disclaimer and the other statements indicating that the Product is not to be used to treat or cure any disease, Plaintiff now alleges that (i) the Product "implicitly claims" to treat the disease of osteoarthritis—notwithstanding that the packaging does not mention osteoarthritis and states that the Product is not intended to treat *any* disease—and therefore (ii) the Product's packaging makes "disease claims," and thus (iii) the Product is actually a misbranded drug under the FDCA and (iv) the Product's labeling therefore violates FDA labeling requirements. Cmplt. ¶¶ 2-6. According to Plaintiff, those alleged violations are "further evidence" of Wal-Mart's alleged unlawful conduct and render the disclaimer both "a legal nullity" and "false and misleading as a matter of law." *Id.* ¶ 7.

The premise for all of these allegations is that the packaging's statements that the Product is "Formulated to help: • Support joint comfort • Rebuild cartilage and lubricate joints" are somehow impermissible "disease claims," rather than permissible "structure/function claims." *Id.* ¶ 4; Ex. A. As discussed below, the FDA regulations and published guidance show otherwise; the language on the Product's packaging is well within the routinely accepted sphere of structure/function claims. Moreover, while Plaintiff states that she does not seek to state a claim under the FDCA (Cmplt. ¶ 7), she conspicuously fails to mention that she *cannot* state a claim under the FDCA because enforcement of the FDCA is expressly reserved for the government. Plaintiff also fails to mention that the FDA has been notified of the statements on the Product's packaging that Plaintiff challenges here, for the specific purpose of reviewing whether the statements are permissible structure/function claims or impermissible disease claims, and the FDA has not asserted any violation of the FDCA or its regulations.

The Causes of Action. Based on the foregoing, Plaintiff asserts claims under California's UCL, the Consumers Legal Remedies Act ("CLRA") and the False Advertising Law ("FAL")[2]

[2] The claim under the FAL is new, but changes nothing. Because the standard for an FAL claim is the same as the standard for a CLRA or a UCL fraudulent prong claim, the FAL claim fails for the same reasons the Court found the CLRA and UCL claims deficient. *Eckler*, 2012

and on behalf of herself and a putative multi-state class of purchasers from states with consumer fraud laws similar to that of California, or a California-only class, of consumers who purchased the Product during the applicable (but unspecified) limitations periods. Cmplt. ¶¶ 41-42.

## ARGUMENT

### I. PLAINTIFF'S CONCLUSORY ALLEGATIONS STILL FAIL TO STATE PLAUSIBLE CLAIMS UNDER RULE 8.

Plaintiff's claims still fail to satisfy Rule 8 because the new Complaint adds no facts that would make the claims facially plausible. Rule 8 requires that a complaint do more than simply *assert* an entitlement to relief; the complaint must include "a short and plain statement of the claim *showing* that the pleader is entitled to relief." Fed. R. Civ. P. 8(a) (emphasis added). To make the requisite "showing," a complaint must allege "sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

While a complaint's factual allegations need not be detailed, they must be sufficient to "'raise a right to relief above the speculative level,'" which means that "'some threshold of plausibility must be crossed at the outset'" before a case can go forward. *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *2-3 (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 558 (2007)). A claim has "'facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.'" *Id.* at *3 (quoting *Iqbal*, 556 U.S. at 678). "The plausibility standard is not akin to a probability requirement, but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Iqbal*, 556 U.S. at 678) (internal quotations omitted).

While a court must draw all *reasonable* inferences in favor of the non-movant, it should not "'necessarily assume the truth of legal conclusions merely because they are cast in the form of factual allegations.'" *Id.* (quoting *Warren v. Fox Family Worldwide, Inc.*, 328 F.3d 1136, 1139 (9th Cir. 2003)). A court need not accept any legal conclusions as true, and a complaint does not

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U.S. Dist. LEXIS 157132, at *29 (citing *Elias v. Hewlett-Packard Co.*, No. 12cv00421, 2012 U.S. Dist. LEXIS 146811, at *24 (N.D. Cal. Oct. 11, 2012)); *id.* at *16 n.5.

suffice "'if it tenders naked assertions devoid of further factual enhancement,'" *id.* (quoting *Iqbal*, 556 U.S. at 678), or if it contains a "merely formulaic recitation of the elements of a cause of action." *Id.* at *4 (citing *Twombly*, 550 U.S. at 555).

The Court dismissed Plaintiff's First Amended Complaint under Rule 8 because there was a fatal "mismatch between the representations at issue and the evidence that allegedly debunks them." *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *28. This Court held:

- First, "[i]t's not really arguing the merits to claim . . . that the studies on which Eckler relies didn't even test the actual formulation of Equate. If that's true, the studies simply wouldn't show what Eckler claims they do, and the Court would be left with no facts from which to infer that Wal-Mart is liable for false advertising." *Id.* at *25.
- Second, "to the extent that Eckler want[s] to frame the representation at issue as promising benefits 'for all stages of joint disease,' it goes straight to the question whether [Eckler's] claims have facial plausibility that a disclaimer explicitly says Equate isn't intended to cure or treat any disease." *Id.* at *25-26.
- Third, "studies allegedly show[ing] that glucosamine doesn't alleviate the symptoms of osteoarthritis in the hip and knee. . . . do[]n't address the far more general claim—which *is* made by the Equate representations—that glucosamine is good for the body's joints." *Id.* at *27.

Plaintiff has not added any allegations to the Second Amended Complaint that alter the Court's earlier reasoning or the consequent conclusion that the claims should be dismissed. Plaintiff is still relying on studies testing certain ingredients in other formulations for treatment of osteoarthritis, a disease the Product was never intended to treat. Plaintiff's theory remains that alleged proof of these other formulations' ineffectiveness in treating osteoarthritis renders the representations on the Product packaging false or misleading. But the Product's packaging does not mention osteoarthritis. To the contrary, the "disclaimer on the packaging says, very clearly, that Equate 'is not intended to diagnose, treat, cure, or prevent *any disease*." *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *13 n.4 (emphasis added); Ex. A. And the Plaintiff still does not (and

cannot) point to any studies that "actually involved Equate," much less test the effectiveness of the Product in providing the benefits actually represented on the Product label. *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *23. The tortured logic, implausible assertions, and unwarranted inferences on which Plaintiff is forced to rely in her Second Amended Complaint in an attempt to tie these osteoarthritis studies to the Product statements demonstrate that dismissal with prejudice is warranted.

Plaintiff Cannot Satisfy Rule 8 By Ignoring the Product's Formulation and Ingredients. Plaintiff purports to limit "the focus of this action" to one ingredient in the Product—glucosamine. Cmplt. ¶ 21 ("the focus of this action is on . . . glucosamine"). Wearing blinders to limit "the focus" may be convenient for Plaintiff because the studies she cites evaluated the effectiveness of only glucosamine alone or in conjunction with chondroitin.[3] But "[a]s its packaging makes clear," Equate actually includes Vitamin C; Vitamin D, Manganese; Sodium; Glucosamine Hydrochloride; a proprietary blend of MSM, Chondroitin Sulfate Sodium, Hydrolyzed Gelatin, *Boswellia Serrata* (wood) resin, and Hyaluronic Acid; and Boron. *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *23. And as the Court recognized, "it is that overall formulation that's behind the representations at issue." *Id.* None of the studies cited by Plaintiff tested that formulation—Plaintiff's assertion that the cited osteoarthritis studies used "the [same] ingredients in the same amounts found in Equate Glucosamine," Cmplt. ¶ 3, is refuted by the Complaint's own allegations describing those studies. *See id.* ¶¶ 24-32.

Plaintiff Cannot Satisfy Rule 8 By Ignoring the Product's Actual Representations. Plaintiff now alleges that "[t]he representations Defendant makes on the labels of Equate . . . are clearly directed at persons suffering from osteoarthritis, who as a result, are the majority of persons who purchase Defendant's Product." *Id.* ¶ 4. But the Product's label, which is before the Court, does *not* refer to osteoarthritis. *See* Ex. A. Plaintiff nevertheless asks the Court to accept the *inference* that Equate is directed at and purchased by osteoarthritis patients based on a citation

[3] Only one study Plaintiff cites evaluated the effectiveness of MSM, but that study did not test the use of MSM in combination with glucosamine, chondroitin or any of the other ingredients in the Product and, like all of Plaintiff's cited studies, it evaluated the use of MSM for treatment of osteoarthritis, rather than for providing any of the benefits actually stated on the Product's label. Cmplt. ¶ 32.

to a medical website that states that the symptoms of osteoarthritis include "'a breakdown of joint cartilage which in turn interferes with joint mobility and causes joint pain and stiffness.'" Cmplt. ¶ 4. Such an inference would not be reasonable here. For one thing, Plaintiff fails to note that the very same website also states that "[t]he symptoms of osteoarthritis may resemble other medical conditions or problems." Osteoarthritis – The University of Chicago Medicine, http://www.uchospitals.edu/online-library/content=P00061 (last visited Dec. 17, 2012). Moreover, the Equate label nowhere refers to "joint pain," which the FDA has determined would be a disease claim. *See infra*, at pp. 11-12. On the contrary, as this Court recognized, "[i]n fact, Equate is marketed as a dietary supplement that 'help[s]' keep joints healthy." *Eckler,* 2012 U.S. Dist. LEXIS 157132, at *28. Indeed, "not only does the packaging state in two places that it's not intended to 'diagnose, treat, cure, or prevent any disease,' it casts Equate as a curative for '[o]verexertion, the natural aging process and everyday wear and tear,' which is yet another way of making this point clear." *Id.*

Obviously, many conditions other than osteoarthritis cause deterioration of joint cartilage, joint stiffness and limited mobility, including "[o]verexertion, the natural aging process and everyday wear and tear." *See* Ex. A. As the label for Equate states, the foregoing "can take their toll," and Equate "helps protect cartilage and helps maintain the cellular components within joints." *Id.* In effect, Plaintiff asks the Court to ignore the label's language and instead infer that any product sold to alleviate any condition or discomfort caused by overexertion, aging or everyday wear and tear that might be somehow similar to some symptom of osteoarthritis is sold as a treatment *for* osteoarthritis (regardless of whether the label even refers to osteoarthritis and regardless of whether the label disclaims the use of the product to treat any disease). By Plaintiff's logic, because many conditions can cause headaches, from tension to a brain tumor, a product sold to alleviate headaches would also be intended to treat patients with brain tumors. Absurd inferences that ignore the actual language on the Equate label do not create a plausible claim for relief.

Plaintiff argues that Equate *implicitly* promises relief to osteoarthritis patients because "no limitations accompany Defendant's joint health benefit representations. The take-away is that

Equate Glucosamine will provide these specific joint related benefits for all joints in the human body, for adults of all ages and for all manner and stages of joint related ailments." Cmplt. ¶ 8. As this Court has already recognized, however, "[i]t's hard to see how the statement 'This product is not intended to diagnose, treat, cure or prevent any disease' is not a qualification or limitation." *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *27 n.9. Plaintiff offers nothing new in her amendment. She persists in attempting to turn logic on its head by suggesting that the Court disregard what the label actually says, and focus on what it does *not* say, and that Equate should be deemed to offer a treatment for a specific *unnamed* disease despite the general disclaimer that Equate expressly is not intended to treat *any* disease. By Plaintiff's logic, product labels would have to list by name every condition or disease the product does *not* treat.

Plaintiff Cannot Satisfy Rule 8 By Insisting that the Product Makes A "Disease Claim" That Cannot Be Found On the Label. Plaintiff now attempts to plead around the clear and express disclaimer with a series of novel allegations that the Product is actually a drug because the label makes disease claims rather than structure/function claims. Cmplt. ¶¶ 2-7. Disease claims are statements that "a product diagnoses, treats, prevents, cures, or mitigates diseases." 65 FR 1000, 1000 (2000). The FDA has identified the criteria it will consider in determining whether a statement is a disease claim, including whether the statement "claims, explicitly or implicitly, that the product . . . [h]as an effect on a specific disease or class of diseases." 21 C.F.R. § 101.93(g) (2012).

Structure/function claims, on the other hand, are statements that "describe[] the role of a nutrient or dietary ingredient intended to affect the structure or function in humans," "characterize[] the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, " or "describe[] general well-being from consumption of a nutrient or dietary ingredient." 21 U.S.C. § 343(r)(6)(A) (2012). "[C]laims concerning the maintenance of 'normal' or 'healthy' structure or function do not imply disease prevention in the context of dietary supplement labeling, unless other statements or pictures in the labeling imply prevention of a specific disease or class of diseases." 65 FR at 1018. An example of a structure/function claim is "calcium builds strong bones." *Id.* at 1008.

A manufacturer of a dietary supplement making a structure/function claim must (i) provide to the FDA "[n]o later than 30 days after the first marketing of a dietary supplement that bears [a structure/function claim]," a notification including, among other things, the text of the claim and the ingredients in the product, and (ii) include a disclaimer on the product that "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease." 21 C.F.R. § 101.93(a)-(c).

Plaintiff points to FDA guidance stating that "'improves joint mobility and *reduces joint inflammation and pain*'" is an implied disease claim relating to arthritis. Cmplt. ¶ 4; *see* 65 FR at 1013 (emphasis added).[4] While that is what is stated in the FDA guidance with reference to "rheumatoid arthritis," that is also *not* what is stated on the Product's label. Rather, the Equate label states "Formulated to help: • Support joint comfort • Rebuild cartilage and lubricate joints." Ex. A. Equate's label nowhere mentions "joint pain" or "inflammation," which both would imply a disease claim.[5] Rather, the Equate label tracks language the FDA has expressly blessed: "FDA also believes that 'joint pain' is characteristic of arthritis. . . . The claim '*helps support cartilage and joint function*,' on the other hand, would be a *permissible structure/function claim*, because it relates to maintaining normal function rather than treating joint pain." 65 FR at 1016-17 (emphasis added); *see also id.* at 1030 ("As explained elsewhere in this document, joint pain is a characteristic symptom of arthritis, and joint pain claims are therefore disease claims."). In

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[4] Plaintiff actually cites an FDA document entitled "Guidance For Industry: Structure/Function Claims, Small Entity Compliance Guide" (Cmplt. ¶ 4) for the proposition that "improves joint mobility and reduces inflammation" is an implied disease claim for rheumatoid arthritis. However, the very document that Plaintiff cites states that it is only a "guidance document" that "restates in plain language the legal requirements in a regulation concerning labeling claims for dietary supplements." *See* FDA, *Guidance For Industry: Structure/Function Claims, Small Entity Compliance Guide*, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/DietarySupplements/ucm103340.htm (Jan. 9, 2002). The full wording of the regulation (which includes the reference to joint "pain") is cited above by Wal-Mart, and it is the "regulations [and not the guidance document that] are binding and have the force and effect of law." *Id.*

[5] Indeed, the very medical website that Plaintiff relies on states that inflammation is the primary characteristic of the disease of rheumatoid arthritis. Rheumatoid Arthritis – The University of Chicago Medicine, http://www.uchospitals.edu/online-library/content=P01133 (last visited Dec. 17, 2012) ("Rheumatoid arthritis is a chronic disease that causes inflammation of the joints.")

contrast to the straw-man example offered in the Complaint, the Equate label not only lacks any reference to "joint pain" or "inflammation," it expressly states that the Product "helps maintain" and is intended for "protecting and maintaining" healthy joints. Ex. A.

Not only does the FDCA not support Plaintiff's claims, but the disclaimer itself is an affirmative requirement of federal law. 21 C.F.R. § 101.93(b). As such, the disclaimer can hardly be "false and misleading as a matter of law." Cmplt. ¶ 7. In any event, even were there no disclaimer, the Product still makes no reference whatsoever to osteoarthritis or to any condition that the FDA has determined to be a reference to osteoarthritis. The disclaimer simply further reinforces the point that the Product is not intended as a cure or treatment for osteoarthritis.[6]

Plaintiff Cannot Satisfy Rule 8 By Relying On Irrelevant Clinical Studies and Misrepresenting Their Findings. Plaintiff selectively and misleadingly quotes the clinical studies cited in the Complaint. Plaintiff broadly claims that the "[c]linical cause and effect studies have found that the primary active ingredient in the Product, glucosamine, when taken alone or in combination with other ingredients, does not provide the joint health benefits represented on the Equate Glucosamine packaging and labeling." *Id.* ¶ 9. In fact, however, even for osteoarthritis patients, the cherry-picked studies Plaintiff cites found that while the evidence for the efficacy of glucosamine is "inconclusive" and "further studies will be needed to resolve the issue of the effectiveness," glucosamine and chondroitin together "significantly decreased knee pain related to osteoarthritis" for patients with "moderate-to-severe pain."[7]

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[6] As explained in Part VI., *infra* at pp. 20-24, Plaintiff's allegations regarding Equate's compliance (or alleged lack thereof) with the FDCA should be stricken because Plaintiff lacks standing to make such allegations, or alternatively referred to the FDA for resolution pursuant to the doctrines of primary jurisdiction or equitable abstention.

[7] Cibere, *et al*., *Randomized, Double Blind, Placebo Controlled Glucosamine Discontinuation Trial in Knee Osteoarthritis*, 51:5 Arthritis & Rheumatism 738, 739 (Oct. 15, 2004) ("[T]he evidence for the efficacy of glucosamine in knee OA is *inconclusive*.") (emphasis added) (cited at Cmplt. ¶ 27 and attached hereto as Ex. B); McAlindon, *et al*., *Effectiveness of Glucosamine for Symptoms of Knee Osteoarthritis: Results from an Internet-Based Randomized Double-Blind Controlled Trial*, 117 Am. J. Med. 643, 648 (Nov. 1, 2004) ("[M]ethodologic issues and sample differences among these trials indicate that further studies will be needed to resolve the issue of the effectiveness of glucosamine products.") (cited at Cmplt. ¶ 24 and attached hereto as Ex. C); Clegg, *et al*., *Glucosamine, Chondroitin Sulfate, and the Two in Combination for Painful Knee Osteoarthritis*, 354:8 New Eng. J. Med. 795, 806 (Feb. 23, 2006) (concluding that glucosamine and chondroitin together "significantly decreased knee pain related to osteoarthritis, as measured by the primary outcome" for patients with "moderate-to-severe

Plaintiff also cites to a 2008 study examining the efficacy of MSM in the treatment of osteoarthritis for the proposition that "scientific studies also confirm that the other ingredients in Equate are ineffective." *Id.* ¶ 32. The only study cited, however, tested one ingredient (MSM) alone, and only for treatment of osteoarthritis, and Plaintiff concedes that the study reached no definitive conclusion. *Id.* ("there is no 'definitive evidence'"). In order to shoehorn that study's findings into her theory, Plaintiff misleadingly excerpts a portion of the article, quoting it as "concluding that there is no 'definitive evidence that MSM is superior to placebo in the treatment of mild to moderate OA of the knee.'" *Id.* What the study actually says, however, is that "*[t]he data from the more rigorous MSM trials provide positive but* not definitive evidence that MSM is superior to placebo in the treatment of mild to moderate OA of the knee." (Emphasis on portion of quote excluded from Complaint).[8] Plaintiff cannot state a plausible theory by simply misrepresenting the findings of the studies and arguing that the Court must accept such blatant mischaracterizations for purposes of a motion to dismiss. *Stanford v. Home Depot U.S.A., Inc.*, No. 07cv2193, 2008 U.S. Dist. LEXIS 112079, at *14 (S.D. Cal. May 27, 2008) (Burns, J.) (court need not accept "'allegations that contradict matters properly subject to judicial notice or by exhibit'" (quoting *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir. 2001))). In any event, Plaintiff's own allegation confirms that the cited study merely failed to find "definitive evidence," which is a far cry from confirming that MSM is "ineffective" even for treatment of osteoarthritis, much less for providing the benefits represented on the Product label.

Emblematic of the disconnect between the findings of the studies and the contention for which Plaintiff cites them is Plaintiff's citation to a 2011 study in support of her argument that Equate is proven ineffective: "The *cost-effectiveness* of [glucosamine chondroitin] dietary supplements . . . in the *treatment of OA* has *not been demonstrated* in North America." Cmplt. ¶ 31 (emphasis added). Nothing in this allegation supports a claim that Equate is proven ineffective: the study did not test Equate or its formulation; the formulation that *was* tested, was

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pain") (cited at Cmplt. ¶ 9 and attached hereto as Ex. D).

[8] S. Brien, *et al., Systematic Review of the Nutritional Supplements Dimethyl Sulfoxide (DMSO) and Methylsulfonylmethane (MSM) in the Treatment of Osteoarthritis*, 16 Osteoarthritis and Cartilage 1277, 1277 (2008) (cited at Cmplt. ¶ 32 and attached hereto as Ex. E)..

tested merely for *cost*-effectiveness in treatment of *osteoarthritis*; and the study merely found that cost-effectiveness in North America "has not been demonstrated." Consequently, even putting aside the fact that the osteoarthritis studies do not address any of the statements actually made on Equate's packaging, the cited studies do not reach any definitive conclusions. At the absolute most, the osteoarthritis studies cited by Plaintiff might support a claim that the effectiveness of Equate (to treat osteoarthritis) is unproven, but that would be a claim for lack of substantiation that a private plaintiff cannot assert as a matter of California law. *See* Part IV., *infra* at pp. 17-18.

Plaintiff Cannot Satisfy Rule 8 By Relying On Unnamed Experts and Unidentified Studies. Finally, unable to show that the Product was intended to treat osteoarthritis, Plaintiff shifts gears and alleges that the cited osteoarthritis studies are relevant even if the Product is *not* intended to treat osteoarthritis because unnamed "experts in the field" believe that osteoarthritis studies are "proxies for whether the ingredients are effective for both arthritic and non-arthritic users of these ingredients," and because "some [of the studies] were performed on 'healthy subjects.'" Cmplt. ¶ 9. Plaintiff cannot salvage her claim (which is subject to Rule 9(b)) by vague and conclusory allegations referring to unnamed experts and unidentified studies.[9]

Plaintiff's "proxy" theory is also facially implausible. Not only is Plaintiff wrong in asserting that the ingredients are proven not to work even for arthritis patients (as discussed below), Plaintiff has it backwards. Even if certain of the ingredients in the Product had not been proven to cure or treat osteoarthritis, that would not support a reasonable inference that those ingredients could not support the maintenance of healthy joints. As this Court held, "studies allegedly show[ing] that glucosamine doesn't alleviate the symptoms of osteoarthritis in the hip and knee. . . . is a very particular showing with respect to a degenerative joint disease, and in the Court's judgment it doesn't address the far more general claim—which *is* made by the

[9] Contrary to Plaintiff's assertion, every study alleged in the Complaint is an osteoarthritis study. *See* ¶ 9 (knee osteoarthritis); ¶ 24 (knee osteoarthritis); ¶ 25 (knee osteoarthritis); ¶ 26 (knee osteoarthritis); ¶ 27 (osteoarthritis); ¶ 28 (hip osteoarthritis); ¶ 29 (osteoarthritis of hip or knee); ¶ 30 (lumbar osteoarthritis) ¶ 31 (cost effectiveness for treatment of osteoarthritis); ¶ 32 (knee osteoarthritis).

[Product's] representations—that glucosamine is good for the body's joints." *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *27.

* * *

In sum, nothing in the Second Amended Complaint should change the Court's conclusion that Plaintiff has not alleged a plausible claim. Accordingly, the new Complaint, like its predecessor, should be dismissed under Rule 8.

## II. PLAINTIFF'S VAGUE ALLEGATIONS FAIL TO STATE CLAIMS WITH THE PARTICULARITY REQUIRED BY RULE 9(b).

The heightened pleading standards of Rule 9(b) also apply to the Complaint. *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *18 n.6 (citing *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009)). "Rule 9(b) demands that, when averments of fraud are made, the circumstances constituting the alleged fraud be specific enough to give defendants notice of the *particular* misconduct [] so that they can defend against the charge and not just deny that they have done anything wrong." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (emphasis added, quotations and citations omitted). Plaintiff's "[a]verments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged." *Id.* Plaintiff "must set forth *more* than the neutral facts necessary to identify the transaction." *Id.* (emphasis in original), quoting *Decker v. Glen Fed, Inc.*, 42 F.3d 1541, 1548 (9th Cir. 1994). She "must set forth what is false or misleading about a statement, and *why* it is false." *Id.* (emphasis added).

While this Court previously concluded that Plaintiff made "an adequate offering of the "'who, what, when, where, and how,'" *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *20 n.6 (internal quotations omitted), Wal-Mart respectfully submits that Plaintiff has failed to adequately plead the "how."

The "how" of Plaintiff's theory of fraud depends entirely on linking the cited osteoarthritis studies to the representations on the Product label. But the statements on the label do not even *mention* osteoarthritis, rather they actively disclaim the Product's use to treat, cure, or prevent *any* disease. Bereft of any plausible link between the studies and the Product, Plaintiff introduces a *deus ex machina*—unidentified experts and studies that will somehow provide Plaintiff with the

link she requires. Cmplt. ¶ 9. Such allegations flout Rule 9(b)'s requirement that the circumstances of the fraud be pled with particularity.

The decision in *Stanley v. Bayer Healthcare LLC*, No. 11cv862, 2012 U.S. Dist. LEXIS 47895 (S.D. Cal. Apr. 3, 2012) is instructive. In *Stanley*, the court found the plaintiff's claim faulty because the plaintiff bought the product to relieve her then-existing bout of diarrhea when the defendant made no representation about relieving (as opposed to preventing) diarrhea. Thus, the plaintiff in *Stanley* bought the product for a purpose that the product was not represented to provide. Here, Plaintiff merely alleges that she purchased Equate "to alleviate stiffness and pain in her shoulder, neck and right wrist." Cmplt. ¶ 16. As discussed above, the Equate label does not promise to relieve "pain" or to treat any disease. If Plaintiff was seeking treatment for the pain of osteoarthritis or another disease, she bought the Product for a purpose the Product was not represented to provide. Plaintiff, however, has not pled anything about her physical condition or why she purchased the Product, leaving the Court and Wal-Mart to speculate. Plaintiff's deliberately vague allegations violate Rule 9(b).

## III. PLAINTIFF STILL FAILS TO PLEAD SUFFICIENT FACTS TO SUPPORT A NON-DISCLOSURE CLAIM.

Plaintiff previously abandoned her non-disclosure claim. *See Eckler*, 2012 U.S. Dist. LEXIS 157132, at *29 (noting that Plaintiff "disavowed" her non-disclosure claim in her brief opposing Wal-Mart's motion to dismiss). To the extent Plaintiff is now seeking to assert such a claim, her allegations remain insufficient. *See* Cmplt. ¶¶ 9, 16, 37, 53-55, 58-61, 69-70, 78.

Plaintiff cannot state a non-disclosure claim under the UCL, FAL, or CLRA without alleging facts giving rise to an affirmative duty to disclose. *See Daugherty v. Am. Honda Motor Co.*, 144 Cal. App. 4th 824, 838 (2006). An omission must concern a fact "defendant was obliged to disclose" or, alternatively, "be contrary to a representation actually made by the defendant." *Id.* at 835. This duty may arise in four circumstances: "(1) when the defendant is in a fiduciary relationship with the plaintiff; (2) when the defendant had exclusive knowledge of material facts not known to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations but also suppresses some

material fact." *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1142 (9th Cir. 2012). None of those circumstances is present in this case.

There is no fiduciary relationship between the parties and the "material facts" are the published clinical trials referenced by Plaintiff in her Complaint. The fact that Plaintiff referenced these studies demonstrates that Wal-Mart did not have exclusive knowledge of them and therefore could not have actively concealed or suppressed them from Plaintiff. Moreover, the studies assess the effectiveness of certain ingredients for the treatment of osteoarthritis, but Wal-Mart never represented that Equate was effective for the treatment of osteoarthritis, so there would have been no reason for Wal-Mart even to consider disclosing the studies. Furthermore, as this Court recognized, "Wal-Mart makes no representation that the purported benefits of Equate have been clinically proven," *Eckler*, 2012 U.S. Dist. LEXIS 157132, at *23 n.7, and thus, there was no obligation to disclose these clinical studies to correct a partial or misleading representation regarding the state of clinical proof. For all of these reasons, Plaintiff has not stated a non-disclosure claim.

## IV. WHEN SHORN OF ITS IMPLAUSIBLE AND CONCLUSORY ALLEGATIONS, THE COMPLAINT ASSERTS NOTHING MORE THAN A NON-COGNIZABLE CLAIM FOR LACK OF SUBSTANTIATION.

Plaintiff directly alleges in the Complaint that "Defendant does not have competent scientific substantiation for its joint health benefit representations . . . ." Cmplt. ¶ 3. *See also id.* ¶ 53 (same). That is a "lack of substantiation" allegation, and "private litigants can't bring those claims." *Eckler*, 2012 U.S.Dist LEXIS 157132, at *4.

In addition to the Complaint's direct allegations of lack of substantiation, Plaintiff *attempts* to allege that the representations on the Product label have "actually been disproved." *Id.* As shown above, however, the only support alleged for these conclusory allegations of falsity and ineffectiveness are irrelevant and inconclusive osteoarthritis studies, none of which found that any representation actually on the label was false or that the Product was ineffective for the purposes for which it was intended. Part I., *supra* at pp. 8-12. Rather, at best for Plaintiff, the handful of osteoarthritis studies handpicked by Plaintiff (while ignoring others) merely were unable to substantiate the existence of a statistically significant benefit for treatment of

osteoarthritis patients over and above the control group. *See id.* at pp. 12-14. Thus, even if studies testing some ingredients for treatment of osteoarthritis were relevant in the first place (they are not), the studies at most suggest that further research is necessary. That is a lack of substantiation claim, and nothing more.

## V. PLAINTIFF FAILS TO STATE A CLAIM UNDER THE UNLAWFUL OR UNFAIR PRONGS OF THE UCL.

The UCL prohibits "any unlawful, unfair or fraudulent business act or practice." Cal. Bus. & Prof. Code § 17200. As this Court noted, "[t]he section is written in the disjunctive, so it establishes three separate and distinct theories of liability," each with different "elements and factual bases." *Eckler*, 2012 U.S. Dist LEXIS 157132, at *13, *15. In dismissing the First Amended Complaint, this Court noted that Plaintiff made "no effort to plead the [UCL] claims independently of one another," and that "[t]he allegations that the representations are 'unlawful' and 'unfair' . . . seem to be thrown in just to plead the claim exhaustively." *Id.* at *15, *17. Because the "core of the claim" was that the representations on the Equate label are false and misleading, the Court held that the claim came under the fraudulent prong. *Id.* at *16. The Court advised Plaintiff that "[i]f, however, she also intends to plead a UCL claim based on unlawful and unfair conduct, she must do more than simply say so." *Id.* at *32. Plaintiff has not met that challenge.

As in the First Amended Complaint, the core of the Second Amended Complaint remains that the representations on the Product are "false, misleading, and, at a minimum, likely to confuse customers purchasing [the] Product." Cmplt. ¶ 4; *see also id.* ¶ 9 ("false, misleading and reasonably likely to deceive the public"); ¶ 12 ("false and misleading"); ¶ 19 ("false, misleading and deceptive"); ¶ 37 ("deceptive"); ¶ 38 ("false and misleading"); ¶ 39 (Plaintiff and class members "were deceived"); ¶ 40 ("false marketing"). Indeed, Plaintiff asserts that "the focus of this action is on the uniform false and deceptive representations." *Id.* at ¶ 21.

Plaintiff still fails to plead sufficient facts to state a claim under either the unlawful or unfair prongs. In its prior order, this Court cautioned Plaintiff that she had alleged only "a formulaic recitation of the elements" of the unlawful and unfair prongs, and that she would need

to plead more to state a claim. *Eckler*, 2012 U.S. Dist LEXIS 157132, at *18. But that is once again all that Plaintiff offers.

As to the unfair prong, Plaintiff again makes the same type of allegations that this Court already held were insufficient. Plaintiff continues to simply parrot the elements of the claim, alleging that "Wal-Mart engaged in immoral, unethical, oppressive and unscrupulous activities that are substantially injurious to consumers." Cmplt. ¶ 54. Plaintiff also still does not "identify the established public policy the alleged misrepresentations violate," *Eckler*, 2012 U.S. Dist LEXIS 157132, at *17, beyond simply stating that the public policy Wal-Mart allegedly violated is the "public policy against engaging in misleading and false advertising, unfair competition, and deceptive conduct." Cmplt. ¶ 55. That, of course, just restates a claim under the fraudulent prong.

As to the unlawful prong, Plaintiff continues to rely on wholly conclusory allegations of violations of California Civil Code §§ 1572, 1573, 1711, and 1770—the same allegations that already led this Court to conclude that "[t]he problems with Eckler's method of pleading [a claim under the unlawful prong] are manifest." *Eckler*, 2012 U.S. Dist LEXIS 157132, at *15 n.5 (noting that each of these provisions has different elements). Plaintiff does now list the specific subsections under §1770 that she alleges were violated, Cmplt. ¶ 53, but again pleads no facts in support of these legal conclusions. And while Plaintiff now asserts that the unlawful prong is satisfied by Wal-Mart's alleged violations of the FDCA and related regulations, *id.*, Plaintiff cannot predicate a UCL claim on alleged violations of the FDCA because "Congress has expressly rejected private rights of action to enforce the FDCA" and therefore "Plaintiffs may not enforce the FDCA privately by using it as a predicate for their UCL claim." *Foli v. Metro. Water Dist.*, No. 11cv1765, 2012 U.S. Dist. LEXIS 50272, at *11 (S.D. Cal. Apr. 10, 2012); *see also* Part VI., *infra* at pp. 20-21. Accordingly, Plaintiff's purported claims under the "unlawful" and "unfair" prongs of the UCL should be dismissed.

## VI. PLAINTIFF'S ALLEGATIONS UNDER THE FDCA SHOULD BE STRICKEN PURSUANT TO RULE 12(f) OR REFERRED TO THE FDA FOR RESOLUTION.

In a further effort to plead around the disclaimer on the Product's label, Plaintiff invokes the FDCA, arguing that the Product's labeling violates various provisions of that law and related federal regulations. While Plaintiff adds that she "does not seek to state a claim under the FDCA" for the alleged violations, she nevertheless invites the Court to find that the Product violates the FDCA, arguing that such violations (i) are "further evidence" of the falsity of the representations on the Product, and (ii) render the disclaimer a "legal nullity" and "false and misleading as a matter of law." Cmplt. ¶¶ 2-7. While the Product label is fully compliant with the FDCA (and Wal-Mart is confident it would prevail were the issue litigated), this suit is not the proper forum for rendering that decision: the Court should either strike those allegations or, pursuant to the doctrines of primary jurisdiction or equitable abstention, refer the issues raised by such allegations to the FDA for resolution.

Plaintiff "does not seek to state a claim under the FDCA" because she *cannot*: enforcement of the FDCA is expressly and exclusively the province of the government. 21 U.S.C. § 337 (2012); *Buckman Co. v. Pl. Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . ."). Plaintiff nevertheless asks the Court to find that Wal-Mart violated the FDCA, and use that finding as support for her UCL and CLRA claims. Cmplt. ¶7. But this is just an attempted end-run around the express bar on private rights of action, and the Court should reject Plaintiff's invitation. As the court in *Perez v. Nidek Co.* held when presented with a similar invitation, "Plaintiffs' claims require the Court to make determinations regarding [compliance with the FDCA]. . . . The court will not permit Plaintiffs to privately enforce the FDCA and its regulations under the guise of [CLRA and UCL] claims." 657 F. Supp. 2d 1156, 1166 (S.D. Cal. 2009). *See also Foli*, 2012 U.S. Dist. LEXIS 50272, at *11 ("Congress has expressly rejected private rights of action to enforce the FDCA" and therefore "Plaintiffs may not enforce the FDCA privately by using it as a predicate for their UCL claim."). The FDA is perfectly capable of taking action if it believes action is warranted. *See, e.g., United*

*States v. Berst*, No. 6:11cv6370, 2012 U.S. Dist LEXIS 135325, at *26-28 (D. Or. Aug 2, 2012) (granting injunction requested by FDA to restrain manufacturer from selling his dietary supplements because the products made disease claims and were therefore unapproved drugs); Press Release, FDA, *Dietary Supplements, unapproved drugs seized in New York* (Oct. 23, 2012), http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm325382.htm (announcing seizure of dietary supplements, including "Glucosamine Plus," for claiming that the dietary supplements would cure or prevent diseases such as osteoarthritis).

Because Plaintiff cannot state a claim for violation of the FDCA, her allegations regarding the FDCA should be stricken from the Complaint. Fed. R. Civ. P. 12(f) ("The court may strike from a pleading . . . any redundant, immaterial, impertinent, or scandalous matter."). While motions to strike are generally disfavored, courts have granted them where a plaintiff has argued that the allegations pertaining to otherwise insufficient or non-cognizable claims "corroborate[], bolster[], and provide[] meaning to and understanding of the [remaining claims]." *Gould v. City of Chicago*, No. 92cv4143, 1993 U.S. Dist. LEXIS 2879, at *2-3 (N.D. Ill. Mar. 9, 1993) (striking allegations in support of claims not raised in Plaintiffs' complaint); *Bradley Trust v. Zenith Capital LLC*, No. C 04-02239, 2006 U.S. Dist. LEXIS 99472, at *9-10 (N.D. Cal. Jan. 24, 2006) (striking allegations referencing fiduciary duties when misrepresentation was the only claim asserted against Defendants). As the court stated in *Gould* in granting a motion to strike, "[b]y their own admission, Plaintiffs' allegations are nothing but superfluous." *Gould*, 1993 U.S. Dist. LEXIS 2879, at *3. That is precisely the case here: the allegations are not made to state a claim under the FDCA (a claim Plaintiff expressly disavows), but rather to somehow "corroborate" and "bolster" Plaintiff's other claims.

Moreover, courts have granted motions to strike similar allegations to avoid a serious risk of prejudice, delay or confusion of the issues. *Fantasy, Inc. v. Fogerty*, 984 F.2d 1524, 1528 (9th Cir. 1993) (affirming trial court's order granting motion to strike allegations where there was a strong likelihood that "the stricken allegations would have unnecessarily complicated the trial," and where striking those allegations "focus[ed] the jury's attention on the real issues in the case."), *rev'd on other grounds*, 510 U.S. 517 (1994); *Bradley Trust*, 2006 U.S. Dist. LEXIS

99472, at *10 ("The possibility that issues will be unnecessarily complicated or that superfluous pleadings will cause the trier of fact to draw unwarranted inferences at trial is the type of prejudice that is sufficient to support the granting of a motion to strike.") Allowing Plaintiff to plead violations of the FDCA where she has no right to pursue such claims would create a serious risk of prejudice to Wal-Mart as it would cause the trier of fact to draw unwarranted inferences that have no bearing on the issues presented in this case. Consequently, this Court should strike Paragraphs 2-7.

In the alternative, this Court should stay or abstain from the litigation of these issues in order to permit the FDA to resolve Plaintiff's allegations regarding compliance with the FDCA. California state courts routinely abstain from deciding UCL, CLRA, and FAL claims where such claims would require the court to adjudicate "complex" regulatory issues better left to administrative agencies "charged with regulating an industry" because those agencies "have better sources of gathering information and assessing its value than do courts in isolated cases." *Alvardo v. Selma Convalescent Hosp.*, 153 Cal. App. 4th 1292, 1295, 1300 (2007) (surveying equitable abstention of UCL, CLRA, and FAL claims).

Federal courts employ a similar doctrine called "primary jurisdiction." The doctrine of primary jurisdiction is a "prudential" doctrine "under which a court determines that an otherwise cognizable claim implicates technical and policy questions that should be addressed in the first instance by the agency with regulatory authority over the relevant industry rather than by the judicial branch." *Clark v. Time Warner Cable*, 523 F.3d 1110, 1114 (9th Cir. 2008). To determine whether the doctrine applies, the Ninth Circuit has typically asked whether there is (i) a need to resolve an issue that (ii) Congress has placed within the jurisdiction of an administrative body with regulatory authority (iii) pursuant to a statute subjecting an industry or activity to a comprehensive regulatory authority that (iv) requires expertise or uniformity in application. *Id.* at 1115. All four factors are met here.

Fundamentally, Plaintiff's allegations would require this Court to determine whether the statements on the Product's label are structure/function claims or not. But that determination is entrusted to the FDA in the first instance, s*ee* 21 U.S.C. § 371, and "[t]he agency has extensive

experience in interpreting such claims" under the FDCA and extensive federal regulations. *See* 65 FR 1000, 1008. Indeed, the FDA held public meetings and spent 18 months reviewing over 235,000 submissions from the dietary supplement industry, trade associations, health professional groups, and consumers to draft a 50-page, single-spaced explanation of the criteria it would use for evaluating whether a claim is a structure/function claim. *See* 65 FR 1000, 1000-02. This Court has neither such time, nor such resources and expertise at its disposal. And were the courts to make *ad hoc* evaluations of whether statements are structure/function claims or disease claims without input from the FDA, the uniformity of enforcement by the FDA would be destroyed, with manufacturers in different locations potentially subject to different labeling requirements. *Cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 (2005) ("Imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings—that would create significant inefficiencies for manufacturers.") The determination of whether the statements on the Product label are structure/function claims should be left to the FDA. *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1177 (9th Cir. 2012) ("[F]or a court to act when the FDA has not—despite regulating extensively in [the food labeling] area—would risk undercutting the FDA's expert judgments and authority."); *Aaronson v. Vital Pharms., Inc.*, No. 09cv1333, 2010 U.S. Dist. LEXIS 14160, *8-9 (S.D. Cal. Feb. 17, 2010) ("[T]he FDA's unique ability to discern scientific data and ensure uniform regulation in the field of dietary supplements weigh in favor of dismissing Aaronson's [UCL and FAL] claims on the grounds of the FDA's primary jurisdiction."); *Perez*, 657 F. Supp. 2d at 1166 (rejecting plaintiff's invitation to determine classification of products under the FDCA because "[t]hese matters should be decided by the FDA in the first instance").

Indeed, the FDA has had at least five years to evaluate the statements on the Product's label. Pursuant to the FDA's regulations, the manufacturer of a dietary supplement must provide "no later than 30 days after the first marketing of a dietary supplement that bears [a structure/function claim]," a statement including, *inter alia*, "[t]he text of the statement that is being made" and "the name of the dietary ingredient or supplement that is the subject of the statement, if not provided in the text of the statement." 21 C.F.R. § 101.93(a). On or about

November 16, 2007, the manufacturer provided the FDA with the required notice, indicating that the proposed structure/function claim for "Glucosamine Chondroitin MSM Complex" stated "Formulated to help: With Joint Comfort[,] Rebuild Cartilage & Lubricate Joints"—a virtually identical product with virtually identical representations as are at issue in this case.[10] *Compare 30-Day Structure Function Claim Notification Letters LET22472 Thru LET22843*, Docket ID FDA-1997-S-0039, Letter 22519, http://www.regulations.gov/#!documentDetail;D=FDA-1997-S-0039-0190 (last visited Dec.4, 2012) (attached hereto as Ex. F) *with* Ex. A. Plaintiff does not allege, nor could she, that the FDA has indicated any objection to this structure/function claim in response to such notification.

## CONCLUSION

For all of the foregoing reasons, the Second Amended Class Action Complaint should be dismissed in its entirety. As demonstrated by Plaintiff's failure to rectify the shortcomings identified in this Court's order dismissing the First Amended Complaint, any further amendment would be futile, and dismissal should now be with prejudice.

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[10] Because the 30-day letter is publicly available from a government entity and can be "readily and accurately determined" from the FDA's website (a source "whose accuracy cannot reasonably be questioned"), this Court may take judicial notice of it in ruling on this motion to dismiss. Fed R. Evid. 201(b); *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (identifying "matters of which a court may take judicial notice" as material "courts ordinarily examine when ruling on Rule 12(b)(6) motions"); *Daniels-Hall v. Nat'l Educ. Ass'n*, 629 F.3d 992, 998-99 (9th Cir. 2010) (taking judicial notice of information which is made publicly available by government entities and where neither party disputes the authenticity of the websites or the accuracy of the information displayed.); *Von Koenig v. Snapple Beverage Corp.*, 713 F. Supp. 2d 1066, 1073 (E.D. Cal. 2010) (taking judicial notice of letters from the FDA on the basis that such letters are matters of public record and available on the FDA website); *Stanford*, 2008 U.S. Dist. LEXIS 112079, at *17 (Burns, J.) (taking judicial notice of documents filed with the government).

Dated: December 17, 2012

DRINKER BIDDLE & REATH LLP

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**PROOF OF SERVICE BY ECF**

STATE OF CALIFORNIA )
) ss.:
COUNTY OF LOS ANGELES )

*Kay Eckler, On Behalf of Herself and All Others Similarly Situated v. Wal-Mart Stores, Inc.*

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action. My business address is 1800 Century Park E, Suite 1400, Los Angeles, CA 90067.

On December 17, 2012, I served on interested parties in said action the within:

**DEFENDANT WAL-MART STORES, INC.'S MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF MOTION TO DISMISS SECOND AMENDED COMPLAINT**

**[Fed. R. Civ. P. 8, 9(b), 12(b)(6)]**

by transmitting a true copy of said document by ECF as stated to all those on the attached service list.

I am readily familiar with the ECF filing system.

Executed on December 17, 2012, at Los Angeles, California.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Elizabeth Woodfork
(Type or print name)

(Signature)

**SERVICE LIST**

*Kay Eckler, On Behalf of Herself and All Others Similarly Situated v. Wal-Mart Stores, Inc.*

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